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and it is likely there will be substantial compliance with that voluntary standard. (See appendix to this part 1115 for a list of such voluntary standards.) This provision applies only when the Commission relies upon a voluntary standard in a rulemaking proceeding under section 9 of the CPSA. In evaluating whether or not to rely upon an existing voluntary standard, the Commission shall adhere to all the procedural safeguards currently required under the provisions of the CPSA, including publication in the FEDERAL REGISTER of the Commission's intent to rely upon a voluntary standard in order to provide the public with a fair opportunity to comment upon such proposed action.

(b) *Reporting requirement.* A firm must report under this section if it has distributed in commerce, subsequent to the effective date of the Consumer Product Safety Improvement Act of 1990 (November 16, 1990), a product that does not conform to a voluntary standard or portion(s) of a voluntary standard relied upon by the Commission since August 13, 1981. If the Commission relied upon only a portion(s) of a voluntary standard, a firm must report under this section only nonconformance with the portion(s) of the voluntary standard relied upon by the Commission. Pursuant to section 7(b)(2) of the CPSA, the Commission shall monitor any modifications of a voluntary standard upon which it has relied and determine, as a matter of policy, at the time any substantive safety related modification is adopted, whether it shall continue to rely upon the former standard or whether it shall rely, subsequently, upon the modified standard. The Commission shall publish such decisions in the FEDERAL REGISTER. Until the Commission makes such a decision, subject firms need not report under this provision a product which complies with either the original version of the voluntary standard relied upon by the Commission or the new version of the standard. A firm must continue to evaluate whether deviations from other portions of a voluntary standard, or other voluntary standards not relied upon by the Commission, either constitute a defect which could create a substantial prod-

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uct hazard or create an unreasonable risk of serious injury or death.

[57 FR 34228, Aug. 4, 1992; 57 FR 39597, Sept. 1, 1992]

§ 1115.6 Reporting of unreasonable risk of serious injury or death.

(a) *General provision.* Every manufacturer, distributor, and retailer of a consumer product distributed in commerce who obtains information which reasonably supports the conclusion that its product creates an unreasonable risk of serious injury or death is required to notify the Commission immediately. 15 U.S.C. 2064(b)(3). The requirement that notification occur when a responsible party “obtains information which reasonably supports the conclusion that” its product creates an unreasonable risk of serious injury or death is intended to require firms to report even when no final determination of the risk is possible. Firms must carefully analyze the information they obtain to determine whether such information “reasonably supports” a determination that the product creates an unreasonable risk of serious injury or death. (See §1115.12(f) for a discussion of the kinds of information that firms must study and evaluate to determine whether they have an obligation to report.) Firms that obtain information indicating that their products present an unreasonable risk of serious injury or death should not wait for such serious injury or death to actually occur before reporting. Such information can include reports from experts, test reports, product liability lawsuits or claims, consumer or customer complaints, quality control data, scientific or epidemiological studies, reports of injury, information from other firms or governmental entities, and other relevant information. While such information shall not trigger a *per se* reporting requirement, in its evaluation of whether a subject firm is required to file a report under the provisions of section 15 of the CPSA, the Commission shall attach considerable significance if such firm learns that a court or jury has determined that one of its products has caused a serious injury or death and a reasonable person could conclude based on the lawsuit and other information obtained by the firm

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that the product creates an unreasonable risk of serious injury or death.

(b) *Unreasonable risk.* The use of the term “unreasonable risk” suggests that the risk of injury presented by a product should be evaluated to determine if that risk is a reasonable one. In determining whether a product presents an unreasonable risk, the firm should examine the utility of the product, or the utility of the aspect of the product that causes the risk, the level of exposure of consumers to the risk, the nature and severity of the hazard presented, and the likelihood of resulting serious injury or death. In its analysis, the firm should also evaluate the state of the manufacturing or scientific art, the availability of alternative designs or products, and the feasibility of eliminating the risk. The Commission expects firms to report if a reasonable person could conclude given the information available that a product creates an unreasonable risk of serious injury or death. In its evaluation of whether a subject firm is required to file a report under the provisions of section 15 of the CPSA the Commission shall, as a practical matter, attach considerable significance if such firm obtains information which reasonably supports the conclusion that its product violates a standard or ban promulgated under the FHSA, FFA, PPPA or RSA and the violation could result in serious injury or death.

(c) *Serious injury or death.* The term “serious injury” is not defined in the CPSA. The Commission believes that the term includes not only the concept of “grievous bodily injury,” defined at § 1115.12(d), but also any other significant injury. Injuries necessitating hospitalization which require actual medical or surgical treatment, fractures, lacerations requiring sutures, concussions, injuries to the eye, ear, or internal organs requiring medical treatment, and injuries necessitating absence from school or work of more than one day are examples of situations in which the Commission shall presume that such a serious injury has occurred. To determine whether an unreasonable risk of serious injury or death exists, the firm should evaluate chronic or

long term health effects as well as immediate injuries.

[57 FR 34228, Aug. 4, 1992]

§ 1115.7 Relation to other provisions.

The reporting requirements of section 37 of the CPSA (15 U.S.C. 2084) are in addition to the requirement in section 15 of the CPSA. Section 37 requires a product manufacturer to report certain kinds of lawsuit information. It is intended as a supplement to, not a substitute for, the requirements of section 15(b) of the CPSA. Whether or not a firm has an obligation to provide information under section 37, it must consider whether it has obtained information which reasonably supports the conclusion that its product violates a consumer product safety rule, does not comply with a voluntary safety standard upon which the Commission has relied under section 9, contains a defect which could create a substantial product hazard, or creates an unreasonable risk of serious injury or death. If a firm has obtained such information, it must report under section 15(b) of the CPSA, whether or not it is required to report under section 37. Further, in many cases the Commission would expect to receive reports under section 15(b) long before the obligation to report under section 37 arises since firms have frequently obtained reportable information before settlements or judgments in their product liability lawsuits.

[57 FR 34229, Aug. 4, 1992]

§ 1115.8 Compliance with product safety standards.

(a) *Voluntary standards.* The CPSA and other federal statutes administered by the Commission generally encourage the private sector development of, and compliance with voluntary consumer product safety standards to help protect the public from unreasonable risks of injury associated with consumer products. To support the development of such consensus standards, Commission staff participates in many voluntary standards committees and other activities. The Commission also strongly encourages all firms to comply with voluntary consumer product safety standards and considers, where